

**NC Division of Medical Assistance  
Outpatient Pharmacy  
Prior Approval Criteria  
Migraine Therapy  
Calcitonin Gene-Related Inhibitors**

**Medicaid and Health Choice  
Effective Date: February 26, 2019  
Amended Date: December 4, 2019**

**Therapeutic Class Code:** H3F

**Therapeutic Class Description:** Migraine Therapy- Calcitonin Gene-Related Peptide Inhibitors

<b>Medication</b>
Aimovig 70mg/ml autoinjector
Aimovig 140mg/ml autoinjector
Ajovy 225mg/1.5ml syringe
Emgality 120mg/ml pen
Emgality 120mg/ml syringe
Emgality 100mg/ml syringe (set of 3)
Emgality 120mg/ml pen

**Eligible Beneficiaries**

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries.**

**EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age**

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or

**NC Division of Medical Assistance  
Outpatient Pharmacy  
Prior Approval Criteria  
Migraine Therapy  
Calcitonin Gene-Related Inhibitors**

**Medicaid and Health Choice  
Effective Date: February 26, 2019  
Amended Date: December 4, 2019**

ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide:***

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

***EPSDT provider page:***

<https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

**Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age**

**EPSDT does not apply to NCHC beneficiaries.** If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

**Indications:** Indicated for the preventative treatment of migraines in adults (Aimovig, Ajovy, and Emgality 120mg/ml) and treatment of episodic cluster headache in adults (Emgality 100mg/ml (set of 3)).

**A. Preventative Treatment of Migraines (Aimovig, Ajovy, and Emgality 120mg/ml)**

**Initial Criteria for Coverage**

1. Beneficiary has a diagnosis of migraine with or without aura based on International Classification of Headache Disorders criteria AND
2. Beneficiary is 18 years old or older AND
3. Beneficiary does not have medication over-use headache (MOH) AND
4. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline AND
5. Beneficiary has 4 or more migraine days per month for at least 3 months AND
6. Beneficiary is utilizing prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) AND
7. Beneficiary has tried and failed at least a month or greater trial of medications from at least 2 different classes from the following list of oral medications:

**NC Division of Medical Assistance**  
**Outpatient Pharmacy**  
**Prior Approval Criteria**  
**Migraine Therapy**  
**Calcitonin Gene-Related Inhibitors**

**Medicaid and Health Choice**  
**Effective Date: February 26, 2019**  
**Amended Date: December 4, 2019**

- a. Antidepressants (e.g. amitriptyline, venlafaxine)
- b. Beta Blockers (e.g. propranolol, metoprolol, timolol, atenolol)
- c. Anti-epileptics (e.g. valproate, topiramate)
- d. Angiotensin converting enzyme inhibitors/angiotensin II receptor blockers (e.g. lisinopril, candesartan)
- e. Calcium Channel Blockers (e.g. verapamil, nimodipine)
8. Initial approvals for up to a 3-month duration for Aimovig, Emgality, Ajovy monthly dosing
9. Initial approvals for up to a 6-month duration for Ajovy quarterly dosing

**Continuation of Coverage (renewal request) (Aimovig, Ajovy, and Emgality 120mg/ml)**

1. Beneficiary has demonstrated significant decrease in the number, frequency, and/or intensity of headaches AND
2. Beneficiary had experienced an overall improvement in function with therapy
3. Beneficiary continues to utilize prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications) AND
4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status AND
5. Beneficiary is not experiencing unacceptable toxicity (e.g. intolerable injection site pain, constipation) AND
6. Length of therapy may be approved for up to 12 months

**B. Treatment of Episodic Cluster Headache in Adults (Emgality 100mg/ml (set of 3))**

**Initial Criteria for Coverage**

1. Beneficiary has a diagnosis of Episodic Cluster Headache with at least two cluster periods lasting from 7 days to 1 year (when untreated) and separated by pain-free remission periods of at least 3 months AND
2. Beneficiary is 18 years old or older AND
3. Beneficiaries that are women of childbearing age have had a negative pregnancy test at baseline AND
4. Beneficiary is utilizing prophylactic intervention modalities (e.g. medication therapy).
5. Beneficiary is receiving no more than 300mg (administered as three consecutive injections of 100mg each) at the onset of the cluster headache period, and then monthly until the end of the cluster headache period.
6. Initial approvals for up to a 3-month duration

**Continuation of Coverage (renewal request) (Emgality 100mg/ml (set of 3))**

1. Beneficiary has demonstrated decreases in the length, number, frequency, and/or intensity of headaches and/or a decrease in the length of the cluster period AND
2. Beneficiary had experienced an overall improvement in function with therapy
3. Beneficiary continues to utilize prophylactic intervention modalities (e.g. behavioral therapy, physical therapy, life-style modifications, medications) AND
4. Beneficiaries that are women of childbearing age continue to be monitored for pregnancy status

**NC Division of Medical Assistance  
Outpatient Pharmacy  
Prior Approval Criteria  
Migraine Therapy  
Calcitonin Gene-Related Inhibitors**

**Medicaid and Health Choice  
Effective Date: February 26, 2019  
Amended Date: December 4, 2019**

AND

5. Beneficiary is not experiencing unacceptable toxicity (e.g. intolerable injection site pain, constipation) AND
6. Length of therapy may be approved for up to 12 months

**References**

1. Aimovig package insert, Amgen, Inc., Thousand Oaks, CA., May 2018.
2. Ajovy package insert, Teva Pharmaceuticals, USA, Inc., North Wales, PA. updated September 2018.
3. Emgality package insert, Eli Lilly and Co., Indianapolis, IN., updated September 2018. updated June 2019

**NC Division of Medical Assistance  
Outpatient Pharmacy  
Prior Approval Criteria  
Migraine Therapy  
Calcitonin Gene-Related Inhibitors**

**Medicaid and Health Choice  
Effective Date: February 26, 2019  
Amended Date: December 4, 2019**

**Criteria Change Log**

02/26/2019	Criteria effective date
12/04/2019	Added coverage for Episodic Cluster Headache in Adults